

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended, 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that: (1) New evidence of clinical experience, not contained in the new drug application or not available to the Commissioner until after the application was approved, evaluated together with the evidence available to him when the application was approved, reveals that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved. The use of gonadotropins of animal origin entails the risk of eliciting the formation of antibodies to their animal protein content so that allergic reactions may be produced by their use. Other drugs are available which are of benefit and involve less risk; and (2) new information, evaluated together with the evidence available to him when the application was approved, shows there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing findings, approval of the above new drug application, and all amendments and supplements applying thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 23, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10263 Filed 7-5-72; 8:48 am]

[DESI 6205; Docket No. FDC-D-425;
NDA 6-205]

PARKE, DAVIS & CO.

Tetraethylammonium Chloride Injection, Notice of Withdrawal of Approval of New Drug Application

A notice was published in the FEDERAL REGISTER of February 12, 1972 (37 F.R. 3201), extending to Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232 and to any interested person who may be adversely affected, an opportunity for hearing on the proposal of the Commissioner of Food and Drugs to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of NDA 6-205 for Etamon Chloride Steri-Vial (tetraethylammonium chloride). The basis of the proposed action was the lack of substantial evidence that the drug is effective for its labeled indications.

Neither the holder of the application nor any other person filed a written appearance of election within the 30 days provided by said notice. The failure to file such an appearance is construed as an election by such persons not to avail themselves of an opportunity for hearing.

The Commissioner of Food and Drugs

pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds that on the basis of new information before him with respect to the drug, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of new drug application No. 6-205 and all amendments and supplements thereto is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10262 Filed 7-5-72; 8:48 am]

SCHERING A.G.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2B2801) has been filed by Schering A.G., 4619 Bergkamen, Postfach 15, Waldstrasse 14, West Germany, proposing that § 121.2602 *Octyltin stabilizers in vinyl chloride plastics* be amended; (1) By revising the specifications for the intermediate, di(*n*-octyl) tin dichloride, to allow for the presence of not more than 5 percent by weight total of higher (>C₈) alkyltin derivatives and (2) by providing for the use of di(*n*-octyl) tin oxide, the product of the intermediate di(*n*-octyl) tin dichloride, as an intermediate in the manufacture of octyltin stabilizers.

Dated: June 27, 1972.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc. 72-10265 Filed 7-5-72; 8:48 am]

[DESI 8089; Docket No. FDC-D-482; NDA 8-089]

WINTHROP LABORATORIES

Glycobiarsol With Chloroquine Phosphate; Notice of Withdrawal of Approval of New Drug Application

In an announcement (DESI 8089) published in the FEDERAL REGISTER of February 19, 1972 (37 F.R. 3779) the Commissioner of Food and Drugs announced his conclusions pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Milibis with Aralen Phosphate Tablets (NDA 8-089) containing glycobiarsol and chloroquine phosphate. The announce-

ment stated that there is a lack of substantial evidence that the drug is effective as a fixed combination for its labeled indications, and that the Commissioner of Food and Drugs intended to initiate proceedings to withdraw approval of the new drug application providing for this drug. Interested persons were invited to submit any pertinent data bearing on the proposal within 30 days following publication of the announcement. No such data have been received. Winthrop Laboratories, Div. of Sterling Drug, Inc., 90 Park Avenue, New York, N.Y. 10016, holder of the new drug application has voluntarily requested withdrawal of approval of their application, thereby waiving their opportunity for a hearing, stating that the drug is no longer marketed.

The Commissioner of Food and Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053, as amended; 21 U.S.C. 355(e)) and under authority delegated to him (21 CFR 2.120), finds on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

Therefore, pursuant to the foregoing finding, approval of the above new drug application, and all amendments and supplements thereto, is withdrawn effective on the date of publication hereof in the FEDERAL REGISTER (7-6-72).

Dated: June 26, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc. 72-10264 Filed 7-5-72; 8:48 am]

Office of the Secretary

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION; OCCUPATIONAL SAFETY AND HEALTH

Requests for Information on Certain Suspected Carcinogenic Substances

Section 20(a)(3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(3)) provides that the Secretary of Health, Education, and Welfare, on the basis of information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment. Section 22(c) of the act authorizes the National Institute for Occupational Safety and Health to develop recommended occupational safety and health standards and to perform all functions of the Secretary of Health, Education, and Welfare, under sections 20 and 21 of the act. The Institute is considering the development of criteria documents and recommended occupational health standards for a number of known and suspected carcinogenic substances including: